

### REMARKS

Reconsideration of the present application is respectfully requested in view of the above amendments and the following remarks. Without acquiescence or prejudice, claim 1 is amended to particularly point out and distinctly claim certain embodiments of Applicants' invention. No new matter has been added by the amendment. Support for the amendment can be found in the specification as filed, for example, at page 11, lines 9-15.

### **REJECTIONS UNDER 35 U.S.C. § 102**

The Examiner rejected claims 1-11, 13-19, 27-37, and 39-45 under 35 U.S.C. § 102(e) for alleged lack of novelty over DeFrees *et al.* (U.S. Patent No. 7,125,843). The Examiner asserts that DeFrees *et al.* disclose a whole antibody conjugated to a biologically active polypeptide. The Examiner then asserts that the whole antibody conjugate of DeFrees *et al.* contains an immunoglobulin Fc **fragment**, and further alleges that given the open language of the instant claims, this conjugated whole antibody falls within the scope of the instant claims.

Applicants traverse this rejection and submit that the instant claims satisfy the requirements of novelty over DeFrees *et al.* Embodiments of the instant claims relate, in pertinent part, to protein conjugates comprising a physiologically active polypeptide, a non-peptide polymer, and an immunoglobulin Fc fragment that “**does not contain the variable regions of the heavy and light chains of the immunoglobulin**,” wherein the peptide and the immunoglobulin Fc fragment are covalently linked through the non-peptide polymer.

DeFrees *et al.* fail to disclose each feature of the instant claims. Mainly, Applicants submit that even in view of the “open” language of the instant claims, the whole antibody conjugates of DeFrees *et al.* do not fall within the scope of these claims, because the presently claimed immunoglobulin Fc **fragments** have been expressly defined to exclude “the variable regions of the heavy and light chains of the immunoglobulin” – structural features that are necessarily present in the whole antibody conjugates of DeFrees *et al.* (*see, e.g.*, column 36, lines 65-37 of DeFrees *et al.*). Hence, the protein conjugates of the instant claims require the presence of an immunoglobulin Fc **fragment** that does not contain “the variable regions of the heavy and light chains of the immunoglobulin,” and which has a physiologically active

polypeptide covalently linked thereto via a non-peptide polymer. DeFrees *et al.* simply do not disclose such a conjugate, because, as noted above, **all** of their whole antibody conjugates necessarily contain “the variable regions of the heavy and light chains of the immunoglobulin” (*see, e.g.*, column 36, lines 65-37; and column 68, last full paragraph of DeFrees *et al.*).

In this light, Applicants kindly point out that the whole antibody conjugates of DeFrees *et al.* do not comprise an Fc **fragment**, as discussed by the Examiner (*see* the Action, page 3). Instead, they merely comprise an Fc **region**, because an Fc **fragment**, as presently claimed, does not contain “the variable regions of the heavy and light chains of the immunoglobulin.” Hence, even if the instant claims are not limited to the specifically recited elements, as also discussed by the Examiner (*see* the Action at page 3), then these claims are still distinguishable from the whole antibody conjugates of DeFrees *et al.*, because of the required presence of such expressly defined immunoglobulin Fc **fragments**. By merely disclosing compositions of **whole antibody** conjugates, it is respectfully submitted that DeFrees *et al.* fail to disclose, inherently or otherwise, a protein conjugate comprising a physiologically active polypeptide, a non-peptide polymer, and an immunoglobulin Fc **fragment** that does not contain “the variable regions of the heavy and light chains of the immunoglobulin,” as presently claimed.

In addition, Applicants kindly submit that the Examiner has not satisfied her burden of proof with regard to the dependent claims, such as by establishing that DeFrees *et al.* disclose each feature of these claims. For instance, dependent claim 2 relates to a protein conjugate of claim 1, wherein the non-peptide polymer is covalently linked via a reactive group at both ends thereof to the physiologically active polypeptide and the immunoglobulin Fc fragment, and claim 11 further recites wherein the reactive group is an aldehyde group, a propione aldehyde group, a butyl aldehyde group, a maleimide group, or a succinimide derivative. Even assuming, *arguendo*, that DeFrees *et al.* disclose conjugating a whole antibody to a peptide via Asn 297, as asserted by the Examiner (*see* the Action, page 3), such a conjugate does not involve the type of linking groups in claim 11, or in claims 13-14 (*see* the diagram at column 67 of DeFrees *et al.*). Applicants, thus, submit that DeFrees *et al.* fail to anticipate these claims.

In view of these amendments and remarks, Applicants submit that the instant claims satisfy the requirements of novelty over this reference, and respectfully request withdrawal of this rejection under 35 U.S.C. § 102(e).

#### **DOUBLE PATENTING REJECTIONS**

The Examiner *provisionally* rejected claims 1-11, 13-19, 27-37, and 39-45 for alleged non-statutory obviousness-type double patenting over claims 1-13 of co-pending U.S. Application No. 10/535,231. The Examiner recognizes that these claims are not identical, but asserts that they are directed to nearly the same polypeptide conjugates and compositions.

Applicants traverse this rejection. As before, since this is a *provisional* rejection, Applicants will address this issue upon the indication of allowable subject matter in this or the other application.

Applicants believe that all of the claims in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,

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